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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/632,748	08/04/2000	Barbara A. Gilcrest	0054.1087-010	2365

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EXAMINER

GUCKER, STEPHEN

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 07/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/632,748Applicant(s)
Gilchrest et al.Examiner
Stephen TuckerGroup Art Unit
1647

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 4/23/03
- ☒ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-10, 12-14, + 16-38 is/are pending in the application.
- Of the above claim(s) 1-9, 12-13, 16-32, 35 + 38 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 10, 14, 33-34, + 36-37 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

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Response to Amendment

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Any objections or rejections made in a previous Office Action that are not herein reinstated have been withdrawn.
3. Newly submitted claims 35 and 38 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: none of the sequences recited as SEQ ID NOs were elected as the species to be examined in Applicant's election, Paper No. 11, filed 8/30/02. The species elected was the peptide comprising the amino acid sequence lysine-glycine-alanine (KGA). If Applicant's wish to have claims narrower in scope searched and examined, Applicants may file a divisional application.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation and Applicant's species election for prosecution on the merits. Accordingly, claims 35 and 38 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

4. Claims 10, 14, 33-34 and 36-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Reams for reasons of record and the following. Reams discloses a method of injecting NGF into the skin of mice, which resulted in a variety of effects on hair growth and pigmentation (Figures 1-7). The process steps of Reams are identical to the process steps of the instant claims,

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and would inherently produce the results claimed by Applicants (see especially the dark hair growth of Figure 3 and the "dense zone of well-formed, black minute hairs" mentioned on page 553), even if Reams does not explicitly set forth the mechanism of action for his results. By injecting NGF directly into the skin of mice, NGF contacted p75 NGFR on melanocytes as it spread from the injection site (Reams, page 556-557), thereby meeting all of the limitations of the instant claims.

Applicant's arguments filed 4/23/03 have been fully considered but they are not persuasive because the prior art teaches the use of NGF, the exact same product used in the process claims of the instant Application, in the exact same manner (contacting melanocytes) as the instant Application. If the Examiner were to agree with Applicant's arguments that the prior art does not meet the instant claim limitations, then the Examiner would be logically forced to conclude that Applicant's invention is not enabled, because Applicant's invention, as claimed, does not exceed or add to the knowledge taught by the prior art concerning the contacting of melanocytes with NGF! Furthermore, Applicant's arguments concerning a quantitative magnitude or amount of "maintaining or inducing hair color" that need be met by the prior art, when the prior art discloses "mixed results," are not persuasive because the claims have no such recited limitations concerning magnitude or amount of the desired effect being produced by the claimed methods. Any positive result, as noted above in the original rejection, meets the claim limitations.

Also see *In re Cruciferous Sprout Litigation*, 64 USPQ2d 1202 (CAFC 2002):

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It is well settled that a prior art reference may anticipate when the claim limitations not expressly found in that reference are nonetheless inherent in it. See, e.g., *Atlas Powder Co. v. IRECO Inc.*, 190 F.3d 1342, 51 USPQ2d 1943 (Fed. Cir. 1999); *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985). "Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates." *MEHL/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362, 1365, 52 USPQ2d 1303, 1305 (Fed. Cir. 1999) (finding anticipation of a method of hair depilation by an article teaching a method of skin treatment but recognizing the disruption of hair follicles, citing *In re King*, 801 F.2d 1324, 1326, 231 USPQ 136, 138 (Fed. Cir. 1986)). "Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art." *MEHL/Biophile*, 192 F.3d at 1365, 52 USPQ2d at 1305-06; *Atlas Powder*, 190 F.3d at 1347, 51 USPQ2d at 1946-47.

5. No claim is allowed.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (703) 308-6571. The examiner can normally be reached on Monday to Friday from 0930 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is currently (703) 308-4242, but Applicant should confirm this by phoning the Examiner before faxing.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SG

Stephen Gucker

July 3, 2003

Gary L. Kunz
GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600